Remarks/Arguments:

Claims 23-28 and 35-46 are pending.

Claims 1-22 and 9-34 are canceled without prejudice or disclaimer.

Claims 26 and 28-40 are amended, hereby in order to more clearly define the invention.

New independent claim 41 contains the subject matter of present claim 23 rewritten to include the subject matter of multiple standardized blood unit doses found in the original claims. Multiple-dose standardization—by itself—is of course well known and defined in the art, e.g., its art-accepted definition "The making of a solution of definite strength so that it may be used for comparison and in tests" set forth in *Standardization Definition from the Online Medical Dictionary*, available online at URL: http://www.mondofacto.com/facts/dictionary?standardization (online printout attached).

New dependent claims 42-46 correspond to present (dependent) claims 36-40, respectively, amended to be dependent (directly or indirectly) on present claim 41.

Claims 23-40 were rejected under 35 USC 112, second paragraph, as allegedly being indefinite. Reconsideration is requested.

The reason for the alleged failure to comply with § 112, ¶ 2, is that "the substance" recited in claims 23 and 35 allegedly has no antecedent basis. With all due respect, the statement of rejection is incorrect.

The preamble in each of claims 23 and 35 reads "A method of testing blood for reaction to a substance" (emphasis added). Accordingly, the "a substance" recited in the preamble of each of

claims 23 and 35 provides the necessary antecedent for "the substance" subsequently recited in each of the claims.

Accordingly, the rejection under § 112, ¶ 2, is overcome and withdrawal of the rejection appears to be in order.

Claims 23-40 were rejected under 35 USC 102(b) as being allegedly anticipated by US 5,364,756 (Livesey). Reconsideration is requested.

Livesey is fatally flawed as a novelty defeating reference (under §102), because Livesey fails to teach—or even suggest—the step of "thawing the cryopreserved unit dose" recited in the rejected claims. The Livesey method does not involve the thawing of a cryopreserved material.

Livesey discloses freeze drying blood cells followed by reconstituting the freeze-dried material. Thus, while the Livesey method does involve cryopreserving blood cells, it does not involve subsequent thawing of the cryopreserving blood cells; rather, the cryopreserved (frozen) blood cells are then dried—i.e., freeze dried—and the dried material is, subsequently, reconstituted. This is clearly evidenced by the Livesey working examples (Example 1, column 20, lines 13-28; Example 2, column 21, lines 1-12; Example 3, column 21, lines 46-58; Example 4, column 22, lines 40-51; Example 5, column 23, lines 45-63). Neither the step of drying nor the step of reconstituting—as taught by Livesey—meets the method step of "thawing the cryopreserved unit dose," to which the rejected claims are limited.

Accordingly, the "absence" from Livesey of a limitation (i.e., the step of thawing the cryopreserved unit dose) on the rejected claims "negates anticipation" of the rejected claims by

Livesey. *Kolster Speed Steel AB v. Crucible Inc.*, 230 USPQ 81, 84 (Fed Cir. 1986). Accordingly, the rejection under §102(b) based on Livesey is overcome and withdrawal of the rejection appears to be in order.

Claims 23-40 were rejected under 35 USC 103 as being allegedly unpatentable over US 4,731,330 (Hill) in view of Livesey. Reconsideration is requested.

As explained, above, Livesey neither teaches nor suggests the limitation "thawing the cryopreserved unit dose" on the rejected claims. Hill adds no disclosure that cures deficiency in the primary reference.

Accordingly, taken alone or in combination, the teachings of Hill and Livesey fail to teach or suggest all limitations on the present claims, which is necessary to establish a prima facie case of obviousness under §103(a). *In re Royka*, 180 USPQ 580 (CCPA 1974). Since "the cited references do not support each limitation of [the present] claim[s]," the rejection under §103(a) is "inadequate on its face" against any of the present claims. *In re Thrift*, 63 USPQ2d 2002, 2008 (Fed. Cir. 2002).

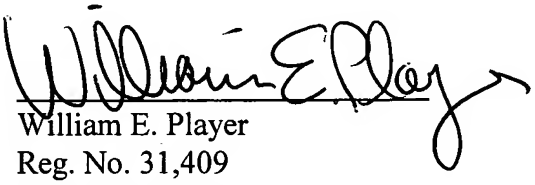
Neither the §102(b) rejection nor the §103(a) rejection is applicable against any of present claims 41-46, for the same reasons set forth above, with respect to the rejected claims; in that present claims 41-46 incorporate the subject matter of rejected claim 23, as explained above. Additionally, neither the rejection under §102(b) nor the rejection under §103(a) is applicable against any of present claims 41-46 for the following reasons.

Present claims 41-46 are limited to (emphasis added) "a collection of multiple identical cryopreserved standardized unit doses." Neither Livesey nor Hill, taken alone or in combination,

teaches or suggests this multiple-dose standardization, i.e., neither reference teaches or suggests a collection of multiple "solution[s] of definite strength so that [each] may be used for comparison and in tests" (*Standardization Definition from the Online Medical Dictionary, supra*).

Favorable action is requested.

Respectfully submitted,



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standardization

medical dictionary

1. The making of a solution of definite strength so that it may be used for comparison and in tests.

2. Making any drug or other preparation conform to the type or standard.

3. A set of techniques used to remove as far as possible the effects of differences in the age or other confounding variables when comparing two or more populations.

Standardization of a test, in psychology, the following of definite procedures for administering, scoring, evaluating, and reporting the results of a new test which is under development.

(05 Mar 2000)